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## **REMARKS**

Claims 1-17 are pending in the application. By this Amendment, claims 1, 2, 7 and 13 are amended. The amendments do not introduce new matter as they are fully supported in the specification. For example, support for the amendments of claims 1, 7 and 13 may be found in the specification on page 8, lines 15-17, and in FIG. 3.

Applicant respectfully requests reconsideration and allowance of all claims in view of the above amendments and following remarks.

The Examiner objected to the specification for incorporating essential material from a publication. It is unclear what the Examiner considers as essential material, if is the properties of the gel, then Applicant respectfully submits that he is <u>not</u> incorporating essential material in the specification. This is because the specification already clearly states on page 8, line 23, to page 9, line 1, that the "[p]roperties of the gel material includ[e] elongation greater than 1,000 percent, low durometer, and high tear strength..." Applicant further indicates that these properties and, more specifically, the formulas of the gel, are further disclosed in Applicant's International Application No. PCT/US01/29682, which was incorporated by reference, and which now has a corresponding U.S. national phase application Serial No. 10/381,220, filed March 20, 2003. Applicant hereby furnishes the Examiner with a copy of the referenced material, PCT/US01/29682, on form PTO/SB/08a for his consideration and review. Thus, Applicant believes that the essential material, i.e., the properties of the gel as opposed to its makeup, is already recited in the specification that does <u>not</u> need to be further

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incorporated from the PCT application. Moreover, it is noted Applicant incorporated by reference a pending international application, which is now in the national phase as indicated above, and that Applicant never incorporated by reference a publication as asserted by the Examiner.

Claims 1 and 13 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,389,080 to Yoon, U.S. Patent No. 5,441,486 to Yoon, and U.S. Patent No. 5,360,417 to Gravener et al. Claims 2-12 and 14-17 were rejected under 35 U.S.C. §102(b) as being anticipated by or, in the alternative, under 35 U.S.C. §103(a) as being obvious over Yoon '080, Yoon '486 and Gravener '417. Applicant respectfully traverses all of the rejections because none of the cited prior art, either alone or in combination, discloses or suggests the claimed invention.

To be anticipating under 35 U.S.C. §102(b), a prior art reference must disclose each and every limitation of the claimed invention, the prior art reference must be enabling, and the prior art reference must describe the claimed invention sufficiently to have placed it in possession of a person of ordinary skill in the field of the invention. Helifix Ltd. v. Blok-Lok, Ltd., 208 F.3d 1339, 54 USPQ2d 1299 (Fed. Cir. 2000). The claimed invention, as amended in claim 1, is directed to an access device in the form of a trocar having a cannula, a housing, and a valve including a gel material. The gel material is unique in having floating or off-axis movement properties for maintaining a seal with a surgical instrument even when the surgical instrument is inserted or moved laterally from the axis of the trocar. Stated another way, a feature of the invention is it allows off-axis insertion or movement of a surgical instrument without the loss of

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insufflation gas. Neither of the Yoon reference nor Gravener discloses this feature of the invention.

Yoon '080 discloses an access device having a portal 10, a housing 25 and a valve assembly 12 including a bladder 36 having a longitudinal passage 38. The bladder 36 operates to conform to the size and configuration of an instrument along the longitudinal passage 38. The bladder 36 has three operational states: a non-expanded or contracted state; a partially filled state with a compressible material such as air, saline, gel, foam or sponge; and a filled or inflated state. None of these states provides features comparable to the floating or off-axis movement properties of the claimed invention. In contrast, all of the operational states of Yoon '080 are along the longitudinal passage 38 such that the bladder 36 may conform to the size and configuration of the instrument after the instrument had been inserted into the access device. There is no indication or suggestion whatsoever of floating or off-axis movement in Yoon '080. As to Yoon '486, it is a divisional of Yoon '080 and discloses an additional tubular portal sleeve 210. Yoon '486 also does not disclose or suggest the floating or off-axis movement of the claimed invention.

Gravener '417 discloses a valve assembly 10 for introduction of surgical instruments into a patient's body including a body 12 formed from a flexibly resilient material which defines an aperture of the instrument. The body 12 defines <u>a central longitudinal aperture 14</u> and further includes a middle portion 28 having substantially cylindrical walls. In the preferred embodiments of Gravener '417, splines 32 are attached at the proximal end of the valve to assist with the insertion of the instrument.

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Gravener '417 further suggests that a gel 42 may be used to bias middle portion 28 along the longitudinal aperture 14, preventing gases and fluids from escaping through the body 12 whether or not an instrument is present in the valve assembly 10. See Col. 4, line 66, to Col. 5, line 1. Similarly to Yoon '080 and '486, Gravener '417 discloses a valve assembly that seals along the longitudal passage or aperture. Again, neither Yoon nor Gravener discloses nor suggests the floating or off-axis properties of the claimed invention. Independent claim 13 also recites similar features to claim 1. For at least the above reasons, Applicant respectfully requests withdrawal of the rejections of claims 1 and 13 under 35 U.S.C. §102(b).

As to claims 2-12 and 14-17, they were rejected either under 35 U.S.C. §102(b) or 35 U.S.C. §103(c) using the same references cited above. Independent claim 7 recites features similar to those of claims 1 and 13; claims 2-6 depend from claim 1; claims 8-12 depend from claim 7; and claims 14-17 depend from claim 13. As explained above, none of the cited prior art discloses each and every limitation of the claimed invention and, as such, Applicant respectfully requests withdrawal of the rejection of claims 2-12 and 14-17 under 35 U.S.C. §102(b). As to the 35 U.S.C. §103(c) rejection, Applicant respectfully submits that each of Yoon '080, Yoon '486 and Gravener '417 is directed to a different invention that is at least functionally different from the claimed invention and, therefore, it would not have been obvious to one skilled in the art at the time of the invention to combine any of the cited prior art to arrive at the claimed invention. Furthermore, there was no suggestion to combine any of these reference. Applicant respectfully submits that none of the cited prior art, either alone or

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in combination, discloses the claimed invention. Accordingly, Applicant respectfully requests withdrawal of the rejection of claims 2-12 and 14-17 under 35 U.S.C. §103(c). Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

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